

Biotech Daily

Wednesday August 20, 2014

Daily news on ASX-listed biotechnology companies

- * ASX UP, BIOTECH DOWN: BIONOMICS UP 7%, GENETIC TECH DOWN 10%
- * CDPP DETAILS OGRU, GIANELLO, JIANG PHOSPHAGENICS INVOICES
- * SIRTEX REVENUE UP 31% to \$131m, PROFIT UP 31% TO \$24m
- * SOUTH AFRICA APPROVAL FOR ACRUX ESTRAMIST FOR MENOPAUSE
- * IDT REVENUE FLAT AT \$13m, LOSS UP 24% TO \$7m
- * COGSTATE REVENUE DOWN 1.2% TO \$12m, LOSS UP 99% TO \$4m
- * BRAIN ADDS 5 US ADDICTION CENTRES

MARKET REPORT

The Australian stock market climbed 0.19 percent on Wednesday August 20, 2014 with the S&P ASX 200 up 10.8 points to 5,634.6 points.

Eight of the Biotech Daily Top 40 stocks were up, 16 fell, nine traded unchanged and seven were untraded. All three Big Caps were up.

Bionomics was the best, up 3.5 cents or 6.6 percent to 56.5 cents with 471,310 shares traded.

Acrux climbed 5.65 percent, Ellex and Nanosonics rose more than four percent; Clinuvel was up three percent; Alchemia and Starpharma rose more than two percent; CSL and Phosphagenics were up more than one percent; with Cochlear and Resmed up by less than one percent.

Genetic Technologies led the falls, down 0.3 cents or 10.3 percent to 2.6 cents with 520.000 shares traded.

Biotron fell 7.1 percent; Analytica and Impedimed lost more than five percent; Benitec and Medical Developments fell more than four percent; both Anteo and Cellmid were down 3.3 percent; GI Dynamics, Optiscan and Prima shed more than two percent; Pharmaxis, Tissue Therapies and Viralytics were down more than one percent; with Mesoblast and Sirtex down by less than one percent.

PHOSPHAGENICS

The Commonwealth Director of Public Prosecutions has alleged a complex web of false invoices was used to defraud Phosphagenics of about \$5 million over nine years.

Appearing before Justice Felicity Hampel in the Melbourne County Court, Allan Sharp for the CDPP, described the issuing of 150 false invoices by companies controlled by former Phosphagenics employee Dr Robert Gianello, 60, of Sassafras and a further 120 invoices by companies associated with former Progen director Dr Woei-Jia Jiang, 51 of Glen Waverly.

Dr Gianello and Dr Jiang formally pleaded guilty to three charges each of dishonestly obtaining financial advantage by deception.

Mr Sharp said that the maximum penalty for each charge was 10 years gaol, but he would be asking for the defendants to be sentenced for their individual benefits, not the total amount obtained by deception.

Mr Sharp alleged that Dr Gianello obtained \$4,635,917 from Phosphagenics and its wholly owned subsidiary Vital Health Services and Dr Jiang obtained \$4,392,035.

Mr Sharp said that as the head of research and development and later as the chief executive officer of Phosphagenics and a director of its wholly-owned subsidiary Vital Health, Dr Esra Ogru approved invoices from Dr Gianello's Bynex Research Services and Pharma Max Pty Ltd as well as Dr Jiang's TABridge Pty Ltd and CK Australia Biotech and Life Sciences Ventures.

Mr Sharp said that Dr Gianello split the proceeds from the false invoices fifty-fifty with Dr Ogru and when Dr Jiang became involved he was asked if he would take 30 percent, with the remainder split evenly between Dr Ogru and Dr Gianello, and Dr Jiang agreed. Mr Sharp said that funds from the invoices were paid to Isikgel and V & E Consulting, companies controlled by Dr Ogru.

Mr Sharp said that Dr Gianello "prepared invoices for work not done and not intended to be done".

"Dr Ogru knew which projects could be invoiced," Mr Sharp told the Court. "She authorized and later approved the payments".

Mr Sharp said that Dr Gianello's false invoices began on November 29, 2004 and continued until the company's new chief financial officer Anna Legg uncovered discrepancies in 2013.

Mr Sharp said that Dr Ogru had claimed that TABridge had supplied vitamin E to Phosphagenics and on May 20, 2013 Ms Legg ordered a stock-take and found a major discrepancy.

Mr Sharp said that in June 2013 Dr Ogru, Dr Gianello and Dr Jiang prepared documents to cover the false TABridge invoices but later that month Dr Ogru "confessed" to co-chief executive officer Harry Rosen and was suspended on July 1, 2013.

Mr Sharp said that Phosphagenics issued proceedings in the Supreme Court of Victoria against the three as well as Dr Gianello's wife, Louise Simpson, a director of one of his companies, and ASIC began investigating on November 11, 2013.

Mr Sharp said that Dr Gianello had personally benefitted by \$677,597 and had used the funds to pay loans and buy investment properties.

Mr Sharp said that Dr Gianello had been declared bankrupt with assets valued between \$377,159 and \$978,238, with Phosphagenics and Vital the major creditors.

Mr Sharp said that Dr Jiang became involved in 2008 when he accidentally sent an email to Dr Ogru, who he met in 1997, but had had little contact between 2001 and 2008. Mr Sharp said that Dr Ogru proposed that Dr Jiang locate off-shore contract research organizations to undertake Phosphagenics and Vital Health work.

Mr Sharp said that Dr Ogru created the invoices for TABridge and Dr Jiang returned them for approval and payment.

Mr Sharp said that Dr Jiang "did not create the TABridge invoices" but agreed with Justice Hampel's summation that "he effectively laundered the money".

Mr Sharp said that on May 1, 2008, Dr Ogru gave birth to a daughter, to be known in the Court as 'Baby Z' who was diagnosed with the fatal disease molybdenum cofactor deficiency type A and a search for a treatment ensued with cyclic pyranopterin monophosphate or cPMP being identified.

Mr Sharp said that over several weeks, Dr Gianello sought to obtain, test and import the compound and on June 6, 2008, Baby Z responded well and it was decided that they would develop the drug, obtained from a Germany company and later sold to the US-based Alexion Pharmaceuticals.

Mr Sharp said there were no legitimate invoices relating to legitimate work that saved Baby Z's life.

Mr Sharp said that from the invoices paid to TABRidge and CK Australia Dr Jiang received a benefit of \$610,800 for his sole use and benefit.

Mr Sharp said that Dr Jiang was paid \$2,000 for each invoice and in April 2010 that was raised to \$3,000 as a fee to launder funds, with Dr Ogru receiving the bulk of the funds.

Mr Sharp said that between 2008 and 2013 TABridge and CK Australia received

\$4,392,035 from Phosphagenics and Vital Health but did not carry out the work invoiced.

Mr Sharp said that Dr Jiang's benefit amounted to \$1,100,026 of which \$250,000 went to his mortgage, \$350,000 to business expenses, \$200,000 into shares, \$200,000 into term deposits and \$100,000 for personal use.

Mr Sharp said that Dr Jiang had repaid Phosphagenics \$1,150,858.

Mr Sharp said that the loss of funds that should have been available to Phosphagenics for research and development was the major issue.

Barrister Kyle McDonald for Dr Gianello told the court that Dr Gianello had agreed to the submission of the invoices, rather than acting alone and submitting them.

Mr McDonald said that Dr Gianello had known Dr Ogru since he was her supervisor at Monash University and she had become his superior and his boss.

Mr McDonald said that Dr Ogru "was persuasive, very charismatic and strong willed" and referred to her television appearances marketing the company's products.

Mr McDonald said the initial payments were to compensate for unpaid overtime, when Dr Gianello was working on Phosphagenics or Vital Health projects at Monash University. Justice Hampel said that "a sense of grievance about unpaid overtime does not justify fraud".

Mr McDonald said that Dr Gianello should have known better, but faced "a gradual slow descent ... a slippery slope" and the invoicing moved from less legitimate to invoicing for work not done and not intended to be done.

Mr McDonald said that two thirds of the \$677,000 obtained by Dr Gianello had gone to "legitimate medical research expenses" on Allan-Herndon-Dudley syndrome trials and although it wasn't his money to use it was "a different level of moral culpability so the level of punishment should not be as severe as if it was for purely selfish personal purposes". Mr McDonald said that Dr Gianello had invested his superannuation and a mortgage into the project and tried to raise funds from friends.

Mr McDonald read a statement from Dr Gianello expressing guilt, remorse and shame at his actions and apologizing to his former colleagues, shareholders and management. The trial was adjourned until tomorrow.

Phosphagenics was up 0.1 cents or one percent to 9.7 cents.

SIRTEX MEDICAL

Sirtex says that revenue for the 12 months to June 30, 2014 was up 30.9 percent to \$131,292,000 with net profit after tax up 30.6 percent to \$23,868,000.

Sirtex said that dose sales increased 17.3 percent to a record 8,561 doses, with sales revenue up 33.7 percent to \$129.4 million.

The company said there were increased dose sales in all regions with the Americas up by 22 percent to 5,836 doses, Europe, the Middle East and Africa up 5.6 percent to 1,916 doses and Asia Pacific up 12.4 percent to 809 doses.

Sirtex chief executive officer Gilman Wong said the company had "delivered another solid result".

"The business continues to go from strength to strength as demand for our targeted liver cancer therapy SIR-Spheres microsphere grows based on an increasingly strong interest from the medical community worldwide," Mr Wong said.

"We believe our current growth rate is sustainable ... however a positive result from our clinical studies should see an acceleration or step change in our growth," Mr Wong said. "We believe Sirtex is still at an early stage in its growth and we remain focused on a range of medium and long-term initiatives aimed at unlocking the full potential of our unique Australian technology platform and building the capabilities and capacity to ensure our leadership position in minimally invasive interventional oncology therapies," Mr Wong said. "The release of our Sirflox study data in 2015 will be an important milestone in our ongoing commercial development of the business," Mr Wong said.

"At the same time, Sirtex is committed to [research and development] and new product innovation in partnership with other industry leaders who share our vision where liver cancer is no longer a terminal disease but a chronic condition people can successfully live with or be cured," Mr Wong said.

The company said that net tangible asset backing per share was constant at 107.3 cents and diluted earnings per share was up 29.1 percent to 41.3 cents for the year to June 30, 2014 compared to 32.0 cents for the previous corresponding period.

The company said that a dividend was yet to be decided but said it paid a fully-franked 12 cent per share dividend for the year to June 30, 2013 on October 25, 2013.

Sirtex said it had in cash and cash equivalents of \$22,495,000 at June 30, 2014, compared to \$20,094,000 at the end of the previous financial year.

Sirtex fell four cents or 0.2 cents to \$20.00 with 256,569 shares traded.

ACRUX

Acrux says the South African Medicines Control Council has granted marketing authorization for its Estramist estradiol spray for menopause symptoms. Acrux said that Estramist was licenced exclusively to Aspen South Africa for that iurisdiction.

The company said that Estramist was marketed in the US as Evamist, with marketing applications under review by regulatory authorities in South Korea and additional European territories.

Acrux executive chairman Ross Dobinson said the company was "pleased that our marketing partner in South Africa has achieved approval for our estradiol product". "We look forward to announcing the product launch and receipt of royalties in due course," Mr Dobinson said.

Acrux was up 10.5 cents or 5.65 percent to \$1.965, with 3.3 million shares traded.

IDT AUSTRALIA

IDT says revenue for the 12 months to June 30, 2014 was flat at \$13,374,000, with a net loss after tax up 23.8 percent to \$6,626,000.

IDT said that net tangible asset per share fell 29.5 percent to 31 cents at June 30, 2014 compared to 44 cents in the previous period.

The company said that diluted loss per share fell 21.5 percent to 9.5 cents compared with 12.1 cents in the previous corresponding period.

IDT said it had cash and equivalents of \$2,415,000 at June 30, 2014 compared to \$578,000 at June 30, 2013.

IDT was untraded at 26 cents.

COGSTATE

Cogstate says revenue for the 12 months to June 30, 2014 fell 1.2 percent to \$12,444,351, with a net loss after tax up 99.0 percent to \$3,888,395.

Cogstate said that net tangible asset per share was up 37.5 percent to 11 cents at June 30, 2014 compared to eight cents in the previous period.

The company said that diluted loss per share was up 65.4 percent to 4.3 cents compared with 2.6 cents in the previous corresponding period.

Cogstate said it had cash and equivalents of \$7,126,749 at June 30, 2014 compared to \$3,392,617 at June 30, 2013.

Cogstate was untraded at 28 cents.

BRAIN RESOURCE

Brain Resource says it has added five new addiction treatment centres, bringing the total number addiction centres using its Mybrainsolutions product to 20 centres.

Brain said the product had been sold into two large US brain health markets, the \$US5 billion a year US corporate employee health programs and the \$US50 billion a year addiction clinics.

The company said that the Mybrainsolutions product was used by clinicians to track and guide their patients' course of rehabilitation and treatment planning.

Brain said the product had a suite of assessment tools and brain training exercises that helped clinicians assess their patients in order to guide their decision-making and helped patients "to manage cravings and build new habits for sober living".

The company said that there were 14,000 addiction centres in the US.

Brain was up one cent or 3.1 percent to 33 cents.